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www.AdvaMed.org



August 4, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Request for Extension of Comment Period; Docket Number 2004N-0264

Dear Sir or Madam:

I am writing on behalf of the Advanced Medical Technology Association (AdvaMed) to request a 30-day extension of the invitation to comment on "Federal Measures to Mitigate BSE Risks: Considerations for Further Action" announced in the July 14, 2004 *Federal Register*. AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,200 members and subsidiaries manufacture nearly 90 percent of the \$75 billion of health care technology products purchased annually in the United States, and more than 50 percent of the \$175 billion purchased annually around the world.

Our member companies manufacture a variety of medical devices utilizing animal-derived materials that will be impacted by the rule that will be developed based on this advanced notice of proposed rulemaking. We believe that we have critical information to contribute to the development of the proposed rule. However, as we are a consensus-driven organization, it takes time to advise our members and collect and organize their input. We asked for a 30-day extension so that we can provide FDA the type of high quality comments we would prefer to submit.

We appreciate your consideration in this matter. You may contact me directly at (202) 434-7267 or cjones@advamed.org.

Sincerely,

A handwritten signature in black ink that reads 'Carolyn D. Jones'.

Carolyn D. Jones
Associate Vice President
Technology and Regulatory Affairs

2004N-0264

EXT 20

COMMAND #066

ADVA MED

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PLEASE DELIVER THE FOLLOWING FACSIMILE

To: Division of Dockets Management / Food and Drug Administration (301) 827 - 6870

From: Carolyn Jones

Date: August 4, 2004

Total number of pages transmitted (including this page): 2 (two)

In case of error in transmission, please notify: Stacey Robertson

Direct Dial: (202) 434-7229

E-Mail: srobertson@advamed.org

MESSAGE --

Please confirm receipt. Thank you.

for Docket Number 2004N-0264